

### AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for ~~a prophylaxis or a treatment of inflammation~~ mediating relaxation of an airway of an animal, said method comprising administering to said animal, an effective amount for said prophylaxis or treatment of a peptide having a sequence comprising SLIGRL (SEQ ID NO:2) or a peptide analog thereof in which ~~one or more~~ an amino ~~acids~~ acid is replaced with non-natural amino acid, wherein said peptide is capable of activating an airway epithelium protease activated receptor-2 (PAR2) under conditions sufficient for activation of said PAR2 to occur, thereby mediating relaxation of said airway.

2. (Previously presented) The method according to Claim 1 wherein the animal is a human.

3. (Canceled)

4. (Canceled)

5. (Previously presented) The method according to Claim 1 wherein the inflammation of the airway is caused by a disease condition selected from the group consisting of asthma, bronchitis, hayfever, alveolitis, ciliary dyskinesia and pulmonary inflammation.

6. (Previously presented) The method according to Claim 1 wherein the peptide comprises the sequence of SEQ ID NO.2.

7. (Previously presented) The method according to Claim 6 wherein the peptide is modified to permit entry across an epithelial and/or subcutaneous layer.

8. (Previously presented) The method according to Claim 7 wherein the peptide is fused to penetratin.

9. (Previously presented) The method according to Claim 7 wherein the peptide is fused to TAT.

Claims 10-19 (Canceled)

20. (Currently amended) A method of identifying an agent for treatment or prophylaxis of inflammation of an airway of an animal, comprising:  
exposing PAR2 to the agent; and

measuring the ability of the agent to activate the PAR2, wherein the agent is identified as capable of being useful for said treatment or prophylaxis of inflammation of an airway of an animal if it does have the ability to activate PAR2.

21. (Previously presented) The method of Claim 1, wherein said peptide incorporates a non-natural amino acid.

22. (Currently amended) The method of Claim 1, wherein said peptide incorporates a non-natural amino acid listed in Table 2 the following table:

<u>Non-conventional amino acid</u>	<u>Code</u>	<u>Non-conventional amino acid</u>	<u>Code</u>
<u><math>\alpha</math>-aminobutyric acid</u>	<u>Abu</u>	<u>L-N-methylalanine</u>	<u>Nmala</u>
<u><math>\alpha</math>-amino-<math>\alpha</math>-methylbutyrate</u>	<u>Mgab</u>	<u>L-N-methylarginine</u>	<u>Nmarg</u>
<u>aminocyclopropane-</u>	<u>Cpro</u>	<u>L-N-methylasparagine</u>	<u>Nmasn</u>
<u>carboxylate</u>		<u>L-N-methylaspartic acid</u>	<u>Nmasp</u>
<u>aminoisobutyric acid</u>	<u>Aib</u>	<u>L-N-methylcysteine</u>	<u>Nmcys</u>
<u>aminonorbornyl-</u>	<u>Norb</u>	<u>L-N-methylglutamine</u>	<u>Nmgln</u>
<u>carboxylate</u>		<u>L-N-methylglutamic acid</u>	<u>Nmglu</u>
<u>cyclohexylalanine</u>	<u>Chexa</u>	<u>L-N-methylhistidine</u>	<u>Nmhis</u>
<u>cyclopentylalanine</u>	<u>Cpen</u>	<u>L-N-methylisoleucine</u>	<u>Nmile</u>
<u>D-alanine</u>	<u>Dal</u>	<u>L-N-methylleucine</u>	<u>Nmleu</u>
<u>D-arginine</u>	<u>Darg</u>	<u>L-N-methyllysine</u>	<u>Nmlys</u>
<u>D-aspartic acid</u>	<u>Dasp</u>	<u>L-N-methylmethionine</u>	<u>Nmmet</u>
<u>D-cysteine</u>	<u>Dcys</u>	<u>L-N-methylnorleucine</u>	<u>Nmnle</u>
<u>D-glutamine</u>	<u>Dgln</u>	<u>L-N-methylnorvaline</u>	<u>Nmnva</u>
<u>D-glutamic acid</u>	<u>Dglu</u>	<u>L-N-methylornithine</u>	<u>Nmorn</u>
<u>D-histidine</u>	<u>Dhis</u>	<u>L-N-methylphenylalanine</u>	<u>Nmphe</u>
<u>D-isoleucine</u>	<u>Dile</u>	<u>L-N-methylproline</u>	<u>Nmpro</u>
<u>D-leucine</u>	<u>Dleu</u>	<u>L-N-methylserine</u>	<u>Nmser</u>
<u>D-lysine</u>	<u>Dlys</u>	<u>L-N-methylthreonine</u>	<u>Nmthr</u>

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<u>D-methionine</u>	<u>Dmet</u>	<u>L-N-methyltryptophan</u>	<u>Nmtrp</u>
<u>D-ornithine</u>	<u>Dorn</u>	<u>L-N-methyltyrosine</u>	<u>Nmtyr</u>
<u>D-phenylalanine</u>	<u>Dphe</u>	<u>L-N-methylvaline</u>	<u>Nmval</u>
<u>D-proline</u>	<u>Dpro</u>	<u>L-N-methylethylglycine</u>	<u>Nmetg</u>
<u>D-serine</u>	<u>Dser</u>	<u>L-N-methyl-t-butylglycine</u>	<u>Nmtbug</u>
<u>D-threonine</u>	<u>Dthr</u>	<u>L-norleucine</u>	<u>Nle</u>
<u>D-tryptophan</u>	<u>Dtrp</u>	<u>L-norvaline</u>	<u>Nva</u>
<u>D-tyrosine</u>	<u>Dtyr</u>	<u><math>\alpha</math>-methyl-aminoisobutyrate</u>	<u>Maib</u>
<u>D-valine</u>	<u>Dval</u>	<u><math>\alpha</math>-methyl-<math>\gamma</math>-aminobutyrate</u>	<u>Mgab</u>
<u>D-<math>\alpha</math>-methylalanine</u>	<u>Dmala</u>	<u><math>\alpha</math>-methylcyclohexylalanine</u>	<u>Mchexa</u>
<u>D-<math>\alpha</math>-methylarginine</u>	<u>Dmarg</u>	<u><math>\alpha</math>-methylcyclopentylalanine</u>	<u>Mcpen</u>
<u>D-<math>\alpha</math>-methylasparagine</u>	<u>Dmasn</u>	<u><math>\alpha</math>-methyl-<math>\alpha</math>-naphthylalanine</u>	<u>Manap</u>
<u>D-<math>\alpha</math>-methylaspartate</u>	<u>Dmasp</u>	<u><math>\alpha</math>-methylpenicillamine</u>	<u>Mpen</u>
<u>D-<math>\alpha</math>-methylcysteine</u>	<u>Dmcys</u>	<u>N-(4-aminobutyl)glycine</u>	<u>Nglu</u>
<u>D-<math>\alpha</math>-methylglutamine</u>	<u>Dmgln</u>	<u>N-(2-aminoethyl)glycine</u>	<u>Naeg</u>
<u>D-<math>\alpha</math>-methylhistidine</u>	<u>Dmhis</u>	<u>N-(3-aminopropyl)glycine</u>	<u>Norn</u>
<u>D-<math>\alpha</math>-methylisoleucine</u>	<u>Dmile</u>	<u>N-amino-<math>\alpha</math>-methylbutyrate</u>	<u>Nmaabu</u>
<u>D-<math>\alpha</math>-methylleucine</u>	<u>Dmleu</u>	<u><math>\alpha</math>-naphthylalanine</u>	<u>Anap</u>
<u>D-<math>\alpha</math>-methyllysine</u>	<u>Dmlys</u>	<u>N-benzylglycine</u>	<u>Nphe</u>
<u>D-<math>\alpha</math>-methylmethionine</u>	<u>Dmmet</u>	<u>N-(2-carbamylethyl)glycine</u>	<u>Ngln</u>
<u>D-<math>\alpha</math>-methylornithine</u>	<u>Dmorn</u>	<u>N-(carbamylmethyl)glycine</u>	<u>Nasn</u>
<u>D-<math>\alpha</math>-methylphenylalanine</u>	<u>Dmphe</u>	<u>N-(2-carboxyethyl)glycine</u>	<u>Nglu</u>
<u>D-<math>\alpha</math>-methylproline</u>	<u>Dmpro</u>	<u>N-(carboxymethyl)glycine</u>	<u>Nasp</u>
<u>D-<math>\alpha</math>-methylserine</u>	<u>Dmser</u>	<u>N-cyclobutylglycine</u>	<u>Ncbut</u>
<u>D-<math>\alpha</math>-methylthreonine</u>	<u>Dmthr</u>	<u>N-cycloheptylglycine</u>	<u>Nchep</u>
<u>D-<math>\alpha</math>-methyltryptophan</u>	<u>Dmtrp</u>	<u>N-cyclohexylglycine</u>	<u>Nchex</u>

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<u>D-<math>\alpha</math>-methyltyrosine</u>	<u>Dmty</u>	<u>N-cyclodecylglycine</u>	<u>Ncdec</u>
<u>D-<math>\alpha</math>-methylvaline</u>	<u>Dmval</u>	<u>N-cylcododecylglycine</u>	<u>Ncdod</u>
<u>D-N-methylalanine</u>	<u>Dnmala</u>	<u>N-cyclooctylglycine</u>	<u>Ncoct</u>
<u>D-N-methylarginine</u>	<u>Dnmarg</u>	<u>N-cyclopropylglycine</u>	<u>Ncpro</u>
<u>D-N-methylasparagine</u>	<u>Dnmasn</u>	<u>N-cycloundecylglycine</u>	<u>Ncund</u>
<u>D-N-methylaspartate</u>	<u>Dnmasp</u>	<u>N-(2,2-diphenylethyl)glycine</u>	<u>Nbhm</u>
<u>D-N-methylcysteine</u>	<u>Dnmcys</u>	<u>N-(3,3-diphenylpropyl)glycine</u>	<u>Nbhe</u>
<u>D-N-methylglutamine</u>	<u>Dnmglu</u>	<u>N-(3-guanidinopropyl)glycine</u>	<u>Narg</u>
<u>D-N-methylglutamate</u>	<u>Dnmglu</u>	<u>N-(1-hydroxyethyl)glycine</u>	<u>Nthr</u>
<u>D-N-methylhistidine</u>	<u>Dnmhis</u>	<u>N-(hydroxyethyl)glycine</u>	<u>Nser</u>
<u>D-N-methylisoleucine</u>	<u>Dnmile</u>	<u>N-(imidazolylethyl)glycine</u>	<u>Nhis</u>
<u>D-N-methylleucine</u>	<u>Dnmleu</u>	<u>N-(3-indolylethyl)glycine</u>	<u>Nhtrp</u>
<u>D-N-methyllysine</u>	<u>Dnmlys</u>	<u>N-methyl-<math>\gamma</math>-aminobutyrate</u>	<u>Nmgabu</u>
<u>N-methylcyclohexylalanine</u>	<u>Nmchexa</u>	<u>D-N-methylmethionine</u>	<u>Dnmmt</u>
<u>D-N-methylornithine</u>	<u>Dnmorn</u>	<u>N-methylcyclopentylalanine</u>	<u>Nmcpn</u>
<u>N-methylglycine</u>	<u>Nala</u>	<u>D-N-methylphenylalanine</u>	<u>Dnmphe</u>
<u>N-methylaminoisobutyrate</u>	<u>Nmaib</u>	<u>D-N-methylproline</u>	<u>Dnmpro</u>
<u>N-(1-methylpropyl)glycine</u>	<u>Nile</u>	<u>D-N-methylserine</u>	<u>Dnmser</u>
<u>N-(2-methylpropyl)glycine</u>	<u>Nleu</u>	<u>D-N-methylthreonine</u>	<u>Dnmthr</u>
<u>D-N-methyltryptophan</u>	<u>Dnmtrp</u>	<u>N-(1-methylethyl)glycine</u>	<u>Nval</u>
<u>D-N-methyltyrosine</u>	<u>Dnmtyr</u>	<u>N-methyl-naphthylalanine</u>	<u>Nmanap</u>
<u>D-N-methylvaline</u>	<u>Dnmval</u>	<u>N-methylpenicillamine</u>	<u>Nmpen</u>
<u><math>\gamma</math>-aminobutyric acid</u>	<u>Gabu</u>	<u>N-(<math>p</math>-hydroxyphenyl)glycine</u>	<u>Nhtyr</u>
<u>L-t-butylglycine</u>	<u>Tbug</u>	<u>N-(thiomethyl)glycine</u>	<u>Ncys</u>
<u>L-ethylglycine</u>	<u>Etg</u>	<u>penicillamine</u>	<u>Pen</u>
<u>L-homophenylalanine</u>	<u>Hphe</u>	<u>L-<math>\alpha</math>-methylalanine</u>	<u>Mala</u>
<u>L-<math>\alpha</math>-methylarginine</u>	<u>Marg</u>	<u>L-<math>\alpha</math>-methylasparagine</u>	<u>Masn</u>

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<u>L-α-methylaspartate</u>	<u>Masp</u>	<u>L-α-methyl-t-butylglycine</u>	<u>Mtbug</u>
<u>L-α-methylcysteine</u>	<u>Mcys</u>	<u>L-methylethylglycine</u>	<u>Metg</u>
<u>L-α-methylglutamine</u>	<u>Mgln</u>	<u>L-α-methylglutamate</u>	<u>Mglu</u>
<u>L-α-methylhistidine</u>	<u>Mhis</u>	<u>L-α-methylhomophenylalanine</u>	<u>Mhphe</u>
<u>L-α-methylisoleucine</u>	<u>Mile</u>	<u>N-(2-methylthioethyl)glycine</u>	<u>Nmet</u>
<u>L-α-methylleucine</u>	<u>Mleu</u>	<u>L-α-methyllysine</u>	<u>Mlys</u>
<u>L-α-methylmethionine</u>	<u>Mmet</u>	<u>L-α-methylnorleucine</u>	<u>Mnle</u>
<u>L-α-methylnorvaline</u>	<u>Mnva</u>	<u>L-α-methylornithine</u>	<u>Morn</u>
<u>L-α-methylphenylalanine</u>	<u>Mphe</u>	<u>L-α-methylproline</u>	<u>Mpro</u>
<u>L-α-methylserine</u>	<u>Mser</u>	<u>L-α-methylthreonine</u>	<u>Mthr</u>
<u>L-α-methyltryptophan</u>	<u>Mtrp</u>	<u>L-α-methyltyrosine</u>	<u>Mtyr</u>
<u>L-α-methylvaline</u>	<u>Mval</u>	<u>L-N-methylhomophenylalanine</u>	<u>Nmhphe</u>
<u>N-(N-(2,2-diphenylethyl)</u>	<u>Nnbhm</u>	<u>N-(N-(3,3-diphenylpropyl)</u>	<u>Nnbhe</u>
<u>carbamylmethyl)glycine</u>		<u>carbamylmethyl)glycine</u>	
<u>1-carboxy-1-(2,2-diphenyl-</u>	<u>Nmbc</u>		
<u>ethylamino)cyclopropane</u>			

23. (Cancelled)

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## **SUMMARY OF INTERVIEW**

### **Identification of Claims Discussed**

Claim 1 was discussed with respect to the enablement, written description, and new matter rejections under 35 U.S.C. § 112, first paragraph. Claim 2 was discussed with respect to the rejection under 35 U.S.C. § 112, first paragraph. Claim 20 was discussed with respect to the new matter rejection under 35 U.S.C. § 112, first paragraph.

### **Proposed Amendments**

Applicants proposed amending the preamble of Claim 1 to recite “[a] method for mediating relaxation of an airway of an animal” so that the endpoint relates back to the preamble.

Applicants proposed amending Claim 1 to recite “an amino acid,” instead of “one or more amino acids.”

### **Principal Arguments and Other Matters**

Applicants argued that amended Claim 1 overcomes the rejections under 35 U.S.C. § 112, first paragraph. The proposed amendment of the preamble “[a] method for mediating relaxation of an airway of an animal” relates the preamble to the endpoint. The amendment of Claim 1 to recite “an amino acid,” instead of “one or more amino acids” addresses enablement, written description, and new matter rejections under 35 U.S.C. § 112, first paragraph.

### **Results of Interview**

Applicants agreed to file an Amendment with an RCE to remove finality. The Amendment would include the proposed amendments discussed during the interview.

The Examiner agreed that Claim 20 was inadvertently rejected under new matter. The Examiner also agreed to review the references submitted with the Response dated October 10, 2004 in evaluating the patentability of Claim 2.